

III. REMARKS

Assignee submits this response to address the issues and concerns raised in the Office Action of August 8, 2008. Claims 1-3, 8, 31, 39-52, 62-72 are pending.

In view of the Examiner's previous restriction requirement and canceled claims, the Assignee asserts the right to present claims 4-7, 9-30, 32-38, and 53-61 in a subsequent continuation application, if desired. Assignee notes that claim status indications of "withdrawn" in parentheses indicate that the referenced claim is being withdrawn without prejudice in response to an earlier restriction requirement.

35 U.S.C. § 112 Concerns

Independent claims 1 and 65 have been amended to clarify that the sperm cells are subjected to the fluid stream pressure associated with a selected fertility characteristic as suggested in the Office Action.

The claims have been clarified to include *inter alia*, "altering flow characteristics of said fluid stream to adjust fluid stream pressure to 30 psi or 40 psi ...". It is respectfully noted that none of the previously cited references show an altering of pressures based on a desired sperm cell fertility characteristic as claimed herein. Further, the Assignee has clearly described the claimed invention in the specification so as to reasonably convey to one skilled in the art that the inventor(s) had possession of the claimed invention at the time of filing. The "altering" step intends to encompass a fluid stream that may be adjusted and perhaps even set to either of two different pressures, namely 40 and 50 psi, depending on the selected desired sperm cell fertility characteristic. For example, sperm cells may be subjected to 40 psi when motility, viability, cleavage rate, or blastocyst rate is selected or sperm cells may be subjected to 30 psi when motility, viability, or pregnancy rate is selected. Adjustment or even altering of fluid stream pressures are well supported in the specification thus supporting that the inventors had well contemplated the adjustment of fluid stream pressures as claimed. Examples from the specification include:

“... the flow characteristics of the stream can be characterized and adjustment means for altering flow characteristics of the fluid stream can be introduced to increase or decrease forces such as compressive forces, sheer forces, or the like, such that particles entrained in the fluid stream can be physically, physiologically, functionally, or mechanically altered.” Paragraph 34 of the application publication no. US2006/0121440A1.

“... alteration of fluid stream characteristics within a flow cytometer or cell sort instrument context can be incrementally adjusted and measured in pounds per square inch and typically allow the incremental increase or decrease in fluid stream pressure between about 20 pounds per square inch and 100 pounds per square inch with a commensurate increase or decrease in fluid stream or sheath fluid velocity.” Paragraph 35 of the application publication no. US2006/0121440A1.

“... altering fluid stream characteristics to incrementally reduce fluid stream pressure, ...can result in a graded series of corresponding sperm cell samples having altered sperm cell fertility characteristics ...” Paragraph 43 of the application publication no. US2006/0121440A1.

Further, it is submitted that one skilled in the art after reviewing the specification could understand that the term, “viability” is used when the sperm are alive. This can be represented in Table 1 where “Live Sperm” show better viability percentages at 30 and 40 psi as compared to 50 psi. Thus, after sperm have been tested under various fluid stream pressures, they are checked to determine how many survived and remain alive. It is also submitted that one skilled in the art after reviewing the specification could understand that the term “cleavage rate” is used when determining if oocytes have cleaved or divided after having been fertilized by the sperm. For example the specification states, “[c]leavage (53.6 and 43.6%) and blastocyst (18.2 and 14.7%) rates were higher for procedures utilizing sperm cells having controlled sperm cell characteristics obtained at about 40 psi than at about 50 psi...” Paragraph 48 of the application

publication no. US2006/0121440A1. The specification also states, “[a]fter injection, oocytes were ... assessed for cleavage ...” Paragraph 49 of the application publication no. US2006/0121440A1.

Therefore, Assignee respectfully submits that the claims comply with the written description requirement, were contemplated at the time the application was filed, and point out and distinctly claim the subject matter which is regarded as the invention.

35 U.S.C. § 102 Concerns

Claims 1 and 65 have been amended to remove the “about” language to clarify that “40 psi” does not include ranges of 50 or even 60 psi. Accordingly, it is respectfully submitted that claims 1 and 65 are not anticipated by the Seidel reference or any other previously cited references since none of them discuss the adjustment of fluid stream pressures as claimed.

Additional Information

The amendments submitted herein should be understood to be made as a practicality only, and should not to be construed as creating any situation of file wrapper estoppel or the like as all rights are expressly reserved and may be pursued in this or other applications, such as divisionals, continuations, or continuations-in-part if desired. Relatedly, it should be understood that the amendments made herein are made for tangential issues of clarity and as a matter of the Office’s convenience or expedience only. The amendments should not be interpreted as an action that in any way surrenders a particular equivalency, surrenders any right to patent coverage, or otherwise limits any rights which the Assignee may now or hereafter assert. It should be understood that, unless and to the extent deemed broadened by this amendment, and even as amended, the Assignee expressly reserves all rights, including but not limited to: all rights to maintain the scope of literal coverage with respect to any element as may have existed under the language previously presented, all rights to maintain the scope of equivalency coverage as may have existed under the language previously presented, and all rights to re-present the prior language at any time in this or any subsequent application. To the extent currently

foreseeable, no change or reduction in direct or equivalency coverage is believed to exist, and no change or reduction in direct or equivalency coverage is intended through the presentation of this amendment.

Further, the office and any third persons interested in potential scope of this or subsequent applications should understand that broader claims may be presented at a later date in this or a continuation in spite of any preliminary amendments, other amendments, claim language, or arguments presented, thus there is not intention to disclaim or surrender any potential subject matter. It should be understood that such broader claims may require that any relevant prior art that may have been considered may need to be re-visited since it is possible that to the extent any amendments, claim language, or arguments presented in this application are considered as made to avoid such prior art, such reasons may be eliminated by later presented claims or the like. Both the examiner and any person otherwise interested in existing or later coverage or considering the possibility of an indication of disclaimer or surrender of potential coverage, should be aware that no such surrender or disclaimer is intended or exists in this application. Limitations such as arose in *Hakim v. Cannon Avent Group, PLC*, 479 F.3d 1313 (Fed. Cir 2007), or the like are expressly not intended in this or any subsequent matter related.

Conclusion

The Assignee believes all concerns raised in the office action have been addressed as best understood and respectfully requests reconsideration and withdrawal of the concerns to the application. Allowance of the claims is requested at the Office's earliest convenience. Should there be any outstanding questions remaining, the Examiner is invited to contact the undersigned.

Dated this 6th day of February, 2009.

Respectfully Submitted,
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